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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/645,426	08/21/2003	Michael Seul	LEAPS-C11	8876
36038	7590	03/25/2008	EXAMINER	
ERIC P. MIRABEZ BIOARRY SOLUTIONS LLC 35 TECHNOLOGY DRIVE WARREN, NJ 07059			DO, PENSEE T	
			ART UNIT	PAPER NUMBER
			1641	
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			03/25/2008	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/645,426	SEUL, MICHAEL	
	Examiner	Art Unit	
	Pensee T. Do	1641	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) Responsive to communication(s) filed on 24 December 2007.
- 2a) This action is **FINAL**. 2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) Claim(s) 76-79 and 81-96 is/are pending in the application.
 - 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) Claim(s) _____ is/are allowed.
- 6) Claim(s) 76-79, 81-96 is/are rejected.
- 7) Claim(s) _____ is/are objected to.
- 8) Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on _____ is/are: a) accepted or b) objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
 - a) All b) Some * c) None of:
 1. Certified copies of the priority documents have been received.
 2. Certified copies of the priority documents have been received in Application No. _____.
 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) Notice of References Cited (PTO-892)
- 2) Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____.
- 4) Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____.
- 5) Notice of Informal Patent Application
- 6) Other: _____.

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114 was filed in this application after a decision by the Board of Patent Appeals and Interferences, but before the filing of a Notice of Appeal to the Court of Appeals for the Federal Circuit or the commencement of a civil action. Since this application is eligible for continued examination under 37 CFR 1.114 and the fee set forth in 37 CFR 1.17(e) has been timely paid, the appeal has been withdrawn pursuant to 37 CFR 1.114 and prosecution in this application has been reopened pursuant to 37 CFR 1.114. Applicant's submission filed on December 24, 2007 has been entered.

Claim Objections

Claims 91 is objected to under 37 CFR 1.75(c) as being in improper form because a multiple dependent claim should refer to other claims in the alternative only. See MPEP § 608.01(n). Accordingly, the claim has not been further treated on the merits.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 76-79, 81-96 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Claim 76 recites a new limitation: "wherein said particles are affixed to said substrate at a density greater than that achieved by bringing the particles within a distance from each other less than the diameter of the particles" which lacks sufficient support from the present specification.

Applicants point out support for this limitation in paragraphs 9 and 48- "finally exhibit a spatial arrangement in the form of a crystalline, or ordered array resembling a raft of bubbles" and "the eventual formation of ordered arrays displaying a hexagonally crystalline configuration in the form of a bubble raft.

However, this is only sufficient to support claim 94, but not the above limitation of claim 76 because:

-the support in the specification is interpreted as: particles are closely packed together in an array that form a bubble raft or a hexagonal crystalline configuration... which means that every particle is in contact with 6 other particles to form a hexagonal crystalline configuration. The particles in the hexagonal crystalline configuration or bubble raft must be in contact with each other.

However, the limitation of claim 76 is interpreted as: the particles can be affixed to the substrate at a greater density but the particles are not necessarily in contact with

each other. For example: if the diameter of the particle is 1 micron, the distance between the particles is 0.6 micron would give a greater density than that of the distance of 0.8 micron. Still the particles separated at 0.6 micron are not in contact with each other.

Therefore, such limitation is not supported by present specification.

It is suggested that applicants recite a similar language from the specification into the claims.

The present specification also fails to support claim 93, wherein an oligonucleotide is used as a chemical tag which fluoresces and is encoded on the beads.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 91, 92 and 93 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 91 depends from claims 76 to 90 which include a canceled claim 80.

Claim 91 is unclear as a dependent claim or independent claim. If it is an independent claim, please recite it clearly. If it is a dependent claim, please change "A" in line 1 to "The".

Claim 92 is rejected for being dependent from claim 91.

Claim 93 is indefinite because it is unclear if the oligonucleotide is attached to some fluorescent somehow fluoresces since claim 76 defines that the chemical characteristic can fluoresce.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 76-79, 81-84, 86-90, 93-96 are rejected under 35 U.S.C. 103(a) as being unpatentable over Margel in view of Singer et al. (5,573,909).

Margel teaches a composition comprising: a) a substrate such as silicon wafer (silicon substrate of claims 84, semiconductor), glass (col. 4, lines 25-31, lines 60-61) in a planar array; b) a population of particles randomly distributed on said sites or wells, said population comprises a plurality of different types of particles with chemical or biochemical binding sites/ligands. (see col. 2, line 35-col. 3, line 5; col. 4, lines 25-65). Regarding claim 88, Margel teaches that immobilization is by chemical bonding or physical bonding. (see col. 3, lines 35-36). The ligands are protein/antibody and biological cells. (see col. 1, lines 40-45; col. 3, lines 23-27). Regarding claim 82, since Margel teaches the use of antibody specific for T-lymphocytes, it is inherent that Margel teaches using monoclonal antibodies because monoclonal antibodies are specific for a cell type. Margel teaches that 1,300 picomoles per squared centimeter protein were

bonded to each of the supported microsphere system (see col. 11, lines 7-9). For claim 95, Margel teaches that the average size of the microspheres range from 300 Angstrom to 8 microns which covers the range of 1 micron to 2 microns for claim 95.

However, Margel fails to teach each type of particle comprises a distinct chemical or biochemical binding site and comprises a unique chemical label; the biochemical binding site comprises a nucleic acid and particles are exposed to a sample containing target analyte. Margel also fails to teach the chemical tag is an oligonucleotide.

Singer teaches microparticles having detectably distinct spectral characteristics of a plurality of dyes incorporated into the microparticles that provide a large and effective Stokes shift, wherein in one example a microparticle-labeled probe emits green fluorescence and another microparticle-labeled probe emits red fluorescence, wherein each microparticle with a distinct spectral characteristic is labeled with a different target complement (biochemical binding sites) to bind with different targets in a sample (claim 89). (see col. 1, lines 32-34, col. 4, lines 37-67, col. 13, lines 53-56; col. 16, lines 54-65). Singer also teaches that the microspheres are polyacrolein or polystyrene and that the target and target complement are antibodies and proteins, respectively. (see col. 13, lines 60-63, col. 16, lines 3 and 31). Singer also teaches that a nucleic acid probe on the microparticles is selective for target nucleic acids. (see col. 14, lines 15-62, col. 16, lines 9-12, and 40-43; col. 18, lines 49-51). For claim 93, Singer teaches that the microparticles are fluorescent and comprises an oligonucleotide. (see col. 26, lines 44-46).

It would have been obvious to one of ordinary skills in the art to modify the composition of Margel with microparticles having distinct spectral characteristics of a plurality of dyes incorporated into the microparticles and each microparticle is labeled with a different target complement for detecting different target materials in a sample, and such target complement is a nucleic acid as taught by Singer, in order to detect one or more variety of target materials including nucleic acids simultaneously and with high sensitivity since both references teach polyacrolein and polystyrene particles that can immobilize antibodies.

However, Margel and Singer fail to teach the particles are affixed to the substrate at a greater density than that achieved by bringing the particles within a distance from each other less than the diameter of the particles; or the density is such that the particles assume a hexagonal configuration and the distances between the particles are the same.

It is well known in the art, as taught by Jack et al. (US 3,989,775) that beads can be packed in a monolayer forming a closely-packed array or hexagonally configuration on a matrix so that maximum density is achieved. Thus, it would have been obvious to one of ordinary skills in the art to arrange beads of equal diameter (as taught by Margel and Singer) in a monolayer forming a closely packed array or hexagonal configuration because when beads are in hexagonally close-packed array, they are at their maximum bead-density. Once the maximum bead density is achieved, maximum density of detection signal can be obtained.

Claim 85 is rejected under 35 U.S.C. 103(a) as being unpatentable over Margel in view of Singer as applied to claim 76 above, and further in view of Nacamulli et al. (US 5,527,710).

Margel and Singer have been discussed above.

However, Margel and Singer fail to teach that the substrate is an electrode.

Nacamulli teaches antigen coated magnetic particles (particle-attached ligands) are deposited uniformly onto the working electrode from a flow stream by placing the magnet directly below. Electrochemiluminescent labeled antibodies are added and the labeled antibodies to the antigens on the magnetic bead immobilized on the surface of the electrode. (see col. 3, lines 10-30).

It would have been obvious to one of ordinary skills in the art to use the electrode taught by Nacamulli as a substrate for use in the composition taught by Margel and Singer since Margel teaches that the population of particles can be immobilized on semiconductor substrate and Singer teaches that the particles are encoded with labels such as fluorescent labels which are the same as electrochemiluminescent labels and Nacamulli teaches that detection ECL labels requires as substrate such as an electrode because electrical pulses are needed to apply in order to modulate the ECL output. The ECL signals are useful in monitoring the rates of binding between the proteins/reactants as well as detecting a low concentration of sample.

Claims 91 and 92 are rejected under 35 U.S.C. 103(a) as being unpatentable over Margel in view of Singer as applied to claim 76 above, and further in view of Gombinski (US 6,297,062).

Margel and Singer have been discussed above.

However, Margel and Singer fail to teach an article of manufacture comprising two or more of any of the array defined in claims 76 to 90; and the location of the array on said substrate in combination with the chemical or physical characteristic indicates the types of ligands therein.

Gombinski teaches a matrix comprising of several arrays comprising particles positioned randomly on those array. (see fig. 2, col. 12, lines 15-31). Gombinski also teaches that the location of the array can be stained with a dye or a label so that it can be identified. (see col. 7, lines 16-20).

It would have been obvious to one of ordinary skills in the art to produce several of the arrays taught by Margel and Singer as suggested by Gombinski to accommodate assays of different types of ligands.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Pensee T. Do whose telephone number is 571-272-0819. The examiner can normally be reached on Monday-Friday, 8:00-4:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Long Le can be reached on 571-272-0823. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Pensee T. Do/
Examiner, Art Unit 1641
March 13, 2008

/Long V Le/
Supervisory Patent Examiner, Art Unit 1641